DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 30, 2015

Asclepion Laser Technologies GmbH
Antje Katzer
Regulatory Affairs Manager
Brüsseler Straße 10
07747 Jena
Germany

Re: K133891
Trade/Device Name: Multipulse Tm+1470
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 27, 2015
Received: January 29, 2015

Dear Ms. Antje Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson
-A

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133891

Device Name

Multipulse Tm+1470

Indications for Use *(Describe)*

The MultiPulse TM+1470 Laser system and its fibre optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including:
Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
Urethral Strictures
Bladder Neck Incisions (BNI)
Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors
Ablation of Benign Prostatic Hypertrophy (BPH)
Transurethral incision of the prostate (TUIP)
Laser Resection of the Prostate (HoLRP)
Laser Enucleation of the Prostate (HoLEP)
Laser Ablation of the Prostate (HoLAP)
Condylomas
Lesions of external genitalia

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Appendectomy
Polyps
Biopsy
Gall Bladder calculi
Biliary/Bile duct calculi
Ulcers
Gastric ulcers
Duodenal ulcers
Non Bleeding Ulcers
Pancreatitas
Hemorrhoids
Cholecystectomy
Benign and Malignant Neoplasm Angiodysplasia
Colorectal cancer
Telangiectasia
Telangiectasia of the Osler-Weber-Renu disease
Vascular Malformation
Gastritis
Esophagitis

Esophageal ulcers
Varices
Colitis
Mallory-Weiss tear
Gastric Erosions

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

Intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and/or vessel coagulation,
Soft tissue excision procedures such as excisional conization of the cervix

ENT
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

Endonasal/sinus Surgery
Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Frontal Sinusotomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery
Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
Tonsillectomy
Adenoidectomy

General surgery
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Cholecystectomy
Lysis of adhesion
Appendectomy
Biopsy
Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy
Pilonidal Cystectomy
Resection of lipoma

Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Statis Ulcer

Arthroscopy
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue):

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including:
Percutaneous Laser Disc Decompression/Discectomy
Foraminoplasty
Ablation and coagulation of soft vascular and nonvascular tissue in minimally invasive spinal surgery

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH K133891
MultiPulse Tm +1470

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MultiPulse Tm+1470 is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
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Preparation Date:	December 10, 2013
Device Name:	MultiPulse Tm +1470
Common Name:	MultiPulse Tm +1470
Classification Name:	Laser surgical instrument for use in general and plastic surgery 79-GEX 21 CFR 878.4810

Equivalent Devices:

Evolve HPD 980/1470 Multiwavelength Diode Laser	K120231
Quanta System Cyber Tm 150 Watt	K102749

Device Description: The MultiPulse Tm+1470 laser system and its fiber optic delivery system is a laser Class IV, operating in CW or pulsed mode. The device is a combination of a Thulium:YAG laser that emits a wavelength of 1940 nm and a near infrared diode laser module that emits a wavelength of 1470 nm. The laser power up to 150 Watts is transmitted through different optical fibers. Besides of the optical bench the device consists of a power supply, a water cooling unit and a control electronic. The device is operated by a touch screen and a foot switch.

Intended Use: The Multipulse Tm +1470 Laser system and its fibre optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:
Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Urethral Strictures

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Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors,

Ablation of Benign Prostatic Hypertrophy (BPH),

Transurethral incision of the prostate (TUIP)

Laser Resection of the Prostate

Laser Enucleation of the Prostate

Laser Ablation of the Prostate

Condyloma

Lesions of external genitalia

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Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Appendectomy

Polyps

Biopsy

Gall Bladder calculi

Biliary/Bile duct calculi

Ulcers

Gastric ulcers

Duodenal ulcers

Non Bleeding Ulcers

Pancreatitis

Hemorrhoids

Cholecystectomy

Benign and Malignant Neoplasma

Angiodysplasia

Colorectal cancer

Telangiectasia

Telangiectasia of the Osler-Weber-Renu disease

Vascular Malformation

Gastritis

Esophagitis

Esophageal ulcers

Varices

Colitis

Mallory-Weiss tear

Gastric Erosions

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) including:

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including:

Percutaneous Laser Disc Decompression/Discectomy

Foraminoplasty

Ablation and coagulation of soft vascular and nonvascular tissue in minimally invasive spinal surgery

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue:

Intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and/or vessel coagulation,

Soft tissue excision procedures such as excisional conization of the cervix

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Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

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Ethmoidectomy

Maxillary antrostomy

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Tonsillectomy

Adenoidectomy

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Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

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Lysis of adhesion

Appendectomy

Biopsy

Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy
Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Statis Ulcer

Substantial Equivalence

The MultiPulse Tm+1470 laser system shares the same indications for use and safety compliance, similar design features, functional features, and therefore is substantially equivalent to the predicate device, the Quanta System Cyber Tm 150W.
The only difference in the specification/characteristic of the MultiPulse Tm+1470 laser system and its predicate Quanta System Cyber Tm 150W is the additional shiftable near diode laser module of 1470 nm. This module can enhance Thulium laser treatment by adding a coagulation effect in cases where hemostasis is desirable.
The MultiPulse Tm+1470 laser system shares the same indications for use and safety compliance, similar design features, functional features, and therefore is substantially equivalent to the predicate device, the Evolve HPD 980/1470nm Multiwavelength Diode Laser. As the MultiPulse Tm+1470, the Evolve device can be operated with an additional wavelength with coagulative effect.

Nonclinical Performance Data:

Laboratory testing was conducted to validate and verify that the MultiPulse Tm+1470 met all design specifications and was substantially equivalent to the predicate device.

Clinical Performance Data: None